

REMARKS

Applicants have amended their claims in order to further clarify the definition of various aspects of the present invention, so as to facilitate proceedings in connection with the above-identified application. Specifically, claim 1 has been amended to recite that the microorganism belongs to *Escherichia coli*, and to recite that this microorganism has resistance to 150 mg/l primaquine and the alkali metal salts thereof. In light of these amendments to claim 1, claims 11 and 12 have been cancelled without prejudice or disclaimer.

Initially, entry of the present amendments is respectfully requested. Noting, for example, previously considered claims 11 and 12, it is respectfully submitted that the present amendments to claim 1 do not raise any new issues, including any issue of new matter. Clearly, in light of previous consideration of claim 11 as in the Amendment filed February 25, 2003, considered by the Examiner in the Office Action mailed May 14, 2003, presently amended claim 1 does not raise any new issues. Furthermore, by incorporating subject matter of claims 11 and 12 into claim 1, it is respectfully submitted that Applicants have materially limited any issues remaining in connection with the above-identified application; and, at the very least, have presented the claims in better form for appeal. Noting arguments set forth infra, it is respectfully submitted that the current amendments present all claims to be considered on the merits in the above-identified application in condition for allowance. In addition, noting previously considered claims 11 and 12 and the comments by the Examiner in the Office Action mailed November 3, 2003, and to facilitate proceedings, it is respectfully submitted that the present amendments are clearly timely.

according to the present invention. General guidelines for practicing the presently claimed method are set forth on page 8 of Applicants' specification; and while a specific example of the microorganism is set forth in the first full paragraph on page 7 of Applicants' specification, it is clear that other microorganisms, including mutant strains, can be used. Note, for example, the paragraph bridging pages 5 and 6, as well as the first and second full paragraphs on page 6 and the paragraph bridging pages 6 and 7, of Applicants' specification. Clearly, it would not constitute undue experimentation to determine materials having resistance to 150 mg/l primaquine or the alkali metal salts thereof, according to the process of the present invention. While some experimentation may be necessary, such experimentation would not be undue; and it is respectfully submitted that only undue experimentation causes a disclosure to be non-enabling. See In re Angstadt, 190 USPQ 214 (CCPA 1976). That is, it is respectfully submitted that one could culture a microorganism and determine its resistance to 150 mg/l primaquine or the alkali metal salts thereof; and, if resistant, and having an ability to produce L-histidine, would be enabling in connection with the presently claimed method. See In re Angstadt, supra.

It is respectfully submitted to be clear from the aforementioned Declaration of T. Abe, submitted September 11, 2003, that one of ordinary skill in the art could obtain a microorganism belonging to *Escherichia coli*, having an ability to produce L-histidine and having resistance to 150 mg/l primaquine or alkali metal salts thereof, without undue experimentation, according to the method described in Applicants' original disclosure. That is, the Declaration shows that three strains (H-9343 strain, No. 1 strain, and No. 2 strain) which are also resistant to 150 mg/l primaquine, have excellent L-histidine productivity as great as or more than H-9341. It is respectfully

submitted that No. 1 strain and No. 2 strain are examples of microorganisms having an ability to produce L-histidine and having resistance to 150 mg/l primaquine or alkali metal salts thereof, which can be obtained according to the method described in the specification of the above-identified application, clearly supporting the conclusion that the original disclosure of the above-identified application would have been enabling as of the filing date of the above-identified application.

The contention by the Examiner that from the data presented it cannot be readily ascertained that a selection with any other aminoquinoline would affect histidine production, since no clear correlation has been provided, is noted. However, it is respectfully submitted that Applicants' disclosure provides a simple test, clearly within the skill of the ordinary worker in the art, for determining materials having the ability to produce L-histidine and having the recited resistance. Clearly, the testing necessary does not constitute "undue" experimentation. Note In re Angstadt, supra.

The contention by the Examiner that strain H-9340 "is clearly required as indicated in the example 1 of the specification, to obtain the further strains touted in the declaration", is noted. However, it is respectfully submitted that Applicants' disclosure as a whole, as originally filed, make it clear to one of ordinary skill in the art that various microorganisms, including various strains from *Escherichia coli*, can be mutated in practicing the presently claimed method. Note also, the paragraph bridging pages 5 and 6 of Applicants' specification, disclosing that microorganisms used in the presently claimed method can be obtained by subjecting a microorganism to a conventional mutation treatment, and selecting colonies of the strain which grow more rapidly than that of the parent strain, or selecting colonies

which are larger than that of the parent strain, among the resulting colonies being cultured. In view of all evidence of record, Applicants respectfully traverse the conclusion by the Examiner in the sentence bridging pages 2 and 3 of the Office Action mailed November 3, 2003, that from the data presented it cannot be readily ascertained that a selection with any other aminoquinoline would effect histidine production; to the contrary, it is respectfully submitted that all the evidence of record, including general guidance provided in Applicants' disclosure, establish that the necessary enablement is provided for the presently claimed subject matter, including culturing a microorganism belonging to *Escherichia coli*, having an ability to produce L-histidine and having resistance to 150 mg/l primaquine or the alkali metal salts thereof.

The contention by the Examiner in the last full paragraph on page 2 of the Office Action mailed November 3, 2003, that there is no clear indication on the record that all restrictions on the availability to the public of the material deposited as FERM BP-6673 will be irrevocably removed upon the granting of a patent, is noted. It is hereby stated by the undersigned that any and all restrictions on the availability to the public of the material deposited as FERM BP-6673 will be irrevocably removed upon the granting of the patent. It is noted that the strain H-9340 was deposited under the Budapest Treaty as FERM BP-6673 as shown in the enclosed "RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT", and it is confirmed by Applicants that all restrictions on the availability to the public of the material deposited as "FERM BP-6673" will be irrevocably removed upon the granting of a patent.

Objection to claim 5 as being dependent upon a rejected base claim, and the indication that this claim would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims, is noted with thanks. Compare, however, with the rejection under the first paragraph of 35 USC §112, wherein claim 5, in addition to claims 1, 11 and 12, is rejected. In any event, it is respectfully submitted that the rejection under the first paragraph of 35 USC §112 should be withdrawn, in view of the presently amended claims, such that all claims being considered on the merits in the above-identified application (that is, claims 1 and 5) should be allowed.

In view of the foregoing comments and amendments, entry of the present amendments, and reconsideration and allowance of all claims presently being considered on the merits in the above-identified application, are respectfully requested.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, or credit any overpayment of fees, to the deposit account of Antonelli, Terry, Stout & Kraus, LLP, Deposit Account No. 01-2135 (referencing case no. 506.39084X00).

Respectfully submitted,


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BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

[特許手続上の微生物の寄託の国際的承認に関するブダペスト条約]

下記国際寄託当局によって規則7.1に従い発行される。

原寄託についての受託証

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT

issued pursuant to Rule 7.1 by the INTERNATIONAL DEPOSITORY AUTHORITY identified at the bottom of this page.

氏名（名称） 協和醸酵工業株式会社
取締役社長 平田 正
寄託者 殿
あて名 東京都千代田区大手町一丁目6番1号

1. 微生物の表示

(寄託者が付した識別のための表示)

Escherichia coli H-9340

(受託番号)

FERM BP- 6673

2. 科学的性質及び分類学上の位置

1欄の微生物には、次の事項を記載した文書が添付されていた。

- 科学的性質
- 分類学上の位置

3. 受領及び受託

本国際寄託当局は、平成11年3月9日（原寄託日）に受領した1欄の微生物を受託する。

4. 移管請求の受領

本国際寄託当局は、 年 月 日（原寄託日）に1欄の微生物を受領した。
そして、 年 月 日に原寄託よりブダペスト条約に基づく寄託への移管請求を受領した。

5. 国際寄託当局

通商産業省工業技術院生命工学工業技術研究所

名 称： National Institute of Bioscience and Human-Technology
Agency of Natural Material Science and Technology

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平成11年(1999) 3月 9日